

REMARKS

The Official Action dated January 16, 2003 has been carefully considered.

Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification and claim 1 are amended for matters of form, while claims 2, 5, 9, 17, 22, 23 and 25 are amended to clarify that the eye components are with respect to an eye in which the correction lens is adapted for implantation. Claim 20 is amended to change its dependency and claims 35 and 40 are amended to stand in independent form. A Version With Markings Showing Changes Made is attached. Claims 49-54 are added. Claims 49 and 50 contain limitations from claim 8, claims 51 and 52 contain limitations from claims 22 and 23, respectively, and claims 53 and 54 correspond with claims 20 and 24 rewritten in independent form. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

At page 3 of the Official Action, the Examiner indicated that claims 20-24 and 35-47 were objected to as being dependent upon a rejected base claim but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 35 and 40 have been amended to stand in independent form, while claims 53 and 54 correspond with claims 20 and 24 written in independent form. It is therefore submitted that claims 35, 40, 53 and 54, and claims 21-23, 36-39, 41-47, 51 and 52 dependent thereon, are in prima facie condition for allowance. Reconsideration is respectfully requested.

Claim 9 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Examiner asserted it is not clear how claim 9 further defines the invention by describing

the radius of the posterior surface to the natural lens when the natural lens is not part of the invention.

This rejection is traversed and reconsideration is respectfully requested. More particularly, claim 9 depends from claim 1 which recites an intraocular correction lens adapted for implantation in the posterior chamber of an eye. Claim 9 recites a property of the central radius of the posterior surface of the optical part of the lens with reference to the central radius of a natural lens in an eye in which the correction lens is adapted for implantation. As claim 1 defines the lens as adapted for implantation in the posterior chamber of an eye, it is believed that the reference in claim 9 to the natural lens of an eye in which the correction lens is adapted for implantation is clear to one of ordinary skill in the art. It is therefore submitted that claim 9 is definite in accordance with the requirements of 35 U.S.C. §112, second paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 1-19, 25, 29-34 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Feingold U.S. Patent No. 6,106,553 in view of the Wanders U.S. Patent No. 6,092,899. Claims 26-28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Feingold and Wanders and further in view of the Choyce U.S. Patent No. 4,414,694. The Examiner asserted that Feingold teaches a conventional concave intraocular lens and in Figure 17 details a non-spherical surface and the Examiner relies on Wanders as teaching that it is conventional and advantageous to form a continuous surface wherein each of the angular zones blends smoothly and without discontinuity into adjacent zones. The Examiner concluded it would have been obvious to modify Feingold, if not inherent, to provide a curved surface free from discontinuities and points of inflection as taught by Wanders. The Examiner relied on Choyce as disclosing a peripheral part with a generally concave portion.

However, Applicants submit that the intraocular correction lenses defined by claims 1-19 and 25-34 and the kit of intraocular lenses defined by claim 48 are nonobvious over and patentably distinguishable from Feingold in view of Wanders, even in further combination with Choyce. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 1, the intraocular correction lenses according to the invention are adapted for implantation in the posterior chamber of an eye between the iris and the intact natural lens. The inventive intraocular correction lens comprises a centrally located optical part capable of providing an optical correction, and a peripherally located supporting element capable of maintaining the optical part in the central location. The optical part and the support element together have a concave posterior surface which is part of a non-spherical surface that is rotation symmetric around the optical axis of the optical part. The intersection between the non-spherical surface and any plane containing the optical axis represents a flawless curve free from discontinuities and points of inflection. The kit of claim 48 comprises intraocular lenses according to claim 1, with a suitable variety of optical powers.

As set forth in the present specification, for example at page 1, lines 5-8, the present intraocular correction lens provides a more anatomical fit in the posterior chamber of the eye, thereby minimizing risks of disturbing the natural lens. As described in further detail at page 7, beginning at line 3, the lens avoids local pressure points which can form stress concentration points or zones on the natural lens of an eye, which may impair the natural metabolism of the natural lens and form local opacifications, leading to cataract formation and the need for surgical intervention. Thus, the intraocular correction lens adapted for implantation in the posterior chamber of an eye between the iris and the intact natural lens as presently claimed provides significant advantages.

Feingold discloses an artificial intraocular refractive correction lens which is implanted into an eye that has a natural crystalline lens. At column 5, lines 4-8, Feingold discloses that at least a part of the posterior surface of the intraocular lens is separated from the anterior of the natural crystalline lens to form a spacing therebetween. At column 6, beginning at line 20, Feingold discloses that the small gap allows for flow of body fluids and minimizes friction. However, Applicants find no teaching, suggestion or recognition by Feingold regarding the surface design of the intraocular lens posterior surface which faces the natural lens, or that such is important in reducing performance problems as discussed above. Figure 17 referenced by the Examiner provides no such teaching, suggestion or recognition. In fact, Feingold does not provide a detailed description regarding the embodiment of Figs. 15-17, and at column 6, Feingold merely discloses that the detailed curvature of the intraocular refractive correction lens is shown in Figure 17. It would appear from Figure 17 that at R8, a point of inflection is disclosed.

On the other hand, Wanders discloses multifocal contact lenses which rest on a cornea and are provided with a reading part and a distance part. Applicants find no teaching or suggestion by Wanders relating to an intraocular lens, particularly adapted for implantation between the iris and the intact natural lens, or relating to the design of the surface of the lens which faces the cornea, i.e., the posterior surface of the lens. While Wanders teaches the shape of the anterior surface of the lens, which faces the eyelid, to be smooth, such a teaching provides no suggestion or motivation for modifying a posterior surface of the intraocular lens of Feingold.

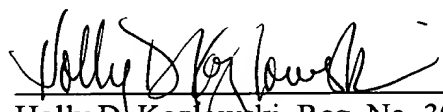
Finally, Choyce discloses an intraocular lens formed entirely of a polysulfone plastics material. However, Applicants find no teaching or suggestion by Choyce relating to the shape of the posterior surface of the lens and, as shown in Fig. 2, the posterior surface of the lens

contains multiple points of inflection. Thus, Choyce does not resolve the deficiencies of Feingold.

In order to render a claimed invention obvious, prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 43 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). In view of the deficiencies in the teachings of Feingold, Wanders and Choyce as discussed above, these references, alone or in combination, do not enable one of ordinary skill in the art to make and use the presently claimed intraocular correction lens. Accordingly, these references do not support the rejections under 35 U.S.C. §103. It is therefore submitted that the intraocular correction lenses defined by claims 1-19 and 25-34 and the kits defined by claim 48 are nonobvious over and patentably distinguishable from Feingold and Wanders, even in further view of Choyce, whereby the rejections under 35 U.S.C. §103 have been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,


Holly D. Kozlowski, Reg. No. 30,468
Dinsmore & Shohl LLP
1900 Chemed Center
255 East Fifth Street
Cincinnati, Ohio 45202
(513) 977-8568

VERSION WITH MARKINGS SHOWING CHANGES MADE

In the Specification:

The paragraph appearing at page 1, lines 5-8 is amended as follows:

--The present invention refers to implantable phakic intraocular lenses (IOLs) suitable as correction lenses together with the intact natural crystalline lens. The inventive lenses [a] are provided with a posterior surface, which admits a more anatomical fit in the posterior chamber of the eye, thereby minimizing the risks of disturbing the natural lens.--

In the Claims:

Claims 1, 2, 5, 9, 17, 21-23, 25, 35 and 40 are amended as follows:

1. (Amended) An intraocular correction lens adapted for implantation in the posterior chamber of [the] an eye between the iris and the intact natural lens, comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining said optical part in said central location, wherein said optical part and said support element together have a concave posterior surface which is part of a non-spherical surface that is rotation symmetric around the optical axis of said optical part, wherein the intersection between said non-spherical surface and any plane containing the optical axis represents a flawless curve free from discontinuities and points of inflection.

2. (Amended) A correction lens according to claim 1, wherein the flawless curve is at least extended in a direction towards the lens periphery within an area defined by the projection of [the] a natural lens in an eye in which the lens is adapted for implantation, on the posterior surface of said correction lens in a direction parallel to the optical axis.

5. (Twice Amended) A correction lens according to claim 2, wherein the supporting element comprises an inner part and a peripheral part designed so as to be at least partially in contact with [the] a ciliary sulcus and [the] zonulas in an eye in which the correction lens is adapted for implantation.

9. (Amended) A correction lens according to claim 1, wherein the central radius of the posterior surface of the optical part is adapted to be different [than] from the central radius of a natural lens in [its] an eye in which the correction lens is adapted for implantation, in a non-accommodated state.

17. (Amended) A correction lens according to claim 16, wherein the three tangentially attached circle segments consist of a centrally located segment having a radius different [to] from that of [the] a natural lens in an eye in which the correction lens is adapted for implantation in its non-accommodated state and two peripheral segments.

21. (Amended) A correction lens according to claim [20] 53, wherein the curve formula is adjusted with one or several additional polynomial factors $a_1r^4 + a_2r^6 + a_3r^8 + a_4r^{10} + \dots + a_nr^{2(n-1)}$, wherein $a_1, a_2, a_3, a_4, \dots, a_n$ are aspheric constants, thereby generating the curve formula $z = cvr^2/(1+\sqrt{(1-cv^2(cc+1)r^2)}) + a_1r^4 + a_2r^6 + a_3r^8 + a_4r^{10} + \dots + a_nr^{2(n-1)}$.

22. (Twice Amended) A correction lens according to claim [20] 53, wherein the flawless curve has a central radius proximal to the optical axis less than the radius of [the] a natural lens in an eye in which the correction lens is adapted for implantation, in its non-accommodated state, said curve substantially following a parabolic or hyperbolic curve formula.

23. (Twice Amended) A correction lens according to claim [20] 53, wherein the flawless curve has a central radius proximal to the optical axis larger than the radius of [the] a natural lens in an eye in which the correction lens is adapted for implantation in its non-accommodated state, said curve substantially following an ellipsoidal curve formula.

35. (Twice Amended) A method of selecting a suitable implantable correction lens [according to claim 1,] for implantation in the posterior chamber of an eye between the iris and the intact natural lens, the correction lens comprising a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining said optical part in said central location, wherein said optical part and said support element together have a concave posterior surface which is part of a non-spherical surface that is rotation symmetric around the optical axis of said optical part, wherein the intersection between said non-spherical surface and any plane containing the optical axis represents a flawless curve free from discontinuities and points of inflection, the method comprising the steps of:

- (i) determining the power of optical correction;
- (ii) estimating the anterior radius of the natural lens in its non-accommodated state;
- (iii) selecting a posterior central radius of the correction lens different from that of the natural lens in its non-accommodated state;
- (iv) determining the total lens vault based on the data arriving from steps (ii) and (iii); and

(v) selecting a flawless curve free from points of inflection representing the interaction of the posterior surface and a plane containing the optical axis so as to provide an aspheric posterior lens surface.

40. (Twice Amended) A method of obtaining a suitable intraocular correction lens implantation for an eye, comprising the steps of:

- (i) determining the power of optical correction;
 - (ii) estimating the anterior radius of the natural lens in its non-accommodated state;
 - (iii) selecting a posterior central radius of the correction lens different from that of the natural lens in its non-accommodated state;
 - (iv) determining the total lens height from the data arriving from steps (ii) and (iii);
- and
- (v) selecting a lens from a kit of correction lenses, wherein each lens is [according to claim 1] adapted for implantation in the posterior chamber of an eye between the iris and the intact natural lens and comprises a centrally located optical part capable of providing an optical correction and a peripherally located supporting element capable of maintaining said optical part in said central location, wherein said optical part and said support element together have a concave posterior surface which is part of a non-spherical surface that is rotation symmetric around the optical axis of said optical part, wherein the intersection between said non-spherical surface and any plane containing the optical axis represents a flawless curve free from discontinuities and points of inflection, said kit containing lenses with a range of different optical powers with dimensional features resulting from the estimation of a suitable average population.